K021358

510(k) SUMMARY AS REQUIRED BY SECTION 807.92(c)

Submitted by:

Irvine Scientific Sales Co., Inc.
2511 Daimler Street
Santa Ana, CA 92705-5588

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Contact: Wendell Lee, Pharm. D.

Date Submitted: April 15, 2002

Device Identification:

Trade Name:	Embryo Biopsy Medium
Common Name:	Embryo Biopsy Medium
Classification Name:	Reproductive Media (21 CFR, 884.6180)

Predicate Device:

Notice of Final Rule, 63 FR 48428, Docket number 97N-0335

Description:

Embryo Biopsy Medium is a defined media intended for use in assisted reproductive technology procedures. It has been formulated to mimic the composition of the fluid found in human fallopian tubes. Embryo Biopsy Medium uses a combination of HEPES/sodium bicarbonate buffering system and is appropriate for those procedures that do not require the use of a carbon dioxide incubator.

Intended Use:

Embryo Biopsy Medium is intended for use during embryo biopsy procedures of human embryos.

Technological Characteristics:

Embryo Biopsy Medium prevents compaction of cleavage-stage embryos and allows for easier separation and removal of 1-2 blastomers during embryo biopsy procedures. Embryo Biopsy Medium contains a combined sodium bicarbonate/HEPES Buffer system to maintain physiological pH in ambient atmosphere (does not require CO_2 incubator).

Performance Data:

Embryo Biopsy Medium is assayed by mouse embryo assay prior to its release to market. This assay assures that the product will not adversely impact embryonic growth and that no toxic components are present. The equivalent of Embryo Biopsy Medium has been used in a variety of clinical settings for the same intended use for a number of years and has become the standard medium used for the fertilization and growth of human gametes and embryos.

Additional Information:

Mouse embryo, endotoxin and sterility testing will be performed as a condition of release for this product. Results of all release assays performed will be indicated on the labeling and reported on a lot-specific certificate of analysis.

Conclusion:

The conclusion from performance testing as well as a review of the historical information contained in professional literature shows that Embryo Biopsy Medium is suitable for the intended use and meets the criteria outlined in the Notice of Final Rule, 63 FR 48428, Docket number 97N-0335.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 5 2002

Wendell Lee, Ph.D.
Quality Systems
and Regulatory Affairs
IRVINE Scientific Sales Co., Inc.
2511 Daimler Street
SANTA ANA CA 92705-5588

Re: K021358
Trade/Device Name: Embryo Biopsy Media
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: 85 MQL
Dated: April 15, 2002
Received: April 29, 2002

Dear Dr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K021358

Device Name: Embryo Biopsy Media

Indications For Use:

Embryo Biopsy Medium is intended for use in assisted reproductive technology procedures that involve the manipulation of embryos. Specifically, Embryo Biopsy Medium is intended for use as a temporary culture medium during embryo biopsy blastomere removal procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021358